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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,545	10/20/1999	GREGORY R. MUNDY	432722002621	4287

25225 7590 03/06/2003  
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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/421,545

Applicant(s)

Mundy et al.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 27, 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-23 is/are pending in the application.
- 4a) Of the above, claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

5 The Corrected Inventorship, Declaration by Mundy and amendment received 11/19/2002, and supplementary amendment received 11/27/2002 have been entered. The amended title is acceptable. The new abstract must be presented on a separate page. Please update the status of related applications in the specification.

10 Priority is claimed to 7/10/1998. Please inform the examiner as to how the present application differs from the two parent applications, 09/361,775 and 09/113,947 to properly confirm the claimed priority date of 7/10/98. No Terminal Disclaimer has been submitted in this file.

15 The request for correction of inventor name is accepted. However, the new declaration containing Rossini's full name is not signed by Mundy.

Claims 1, 5-23 are currently pending in this application, claims 8-18 have not been canceled.

20 This application contains claims 8-18 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

In view of the arguments presented, the rejection of record under 35 USC 103(a) is hereby withdrawn.

Regarding the restriction requirement of 6/20/2001, Groups I and V are independent and distinct inventions. Group V, claim 18 would require an entirely different search than the claims of Group I, 1-7 originally.

5           Regarding the two Forms PTO-1449 submitted 3/14/2000 and 9/10/2001, the references have not been considered because they are not found in this file and are not all readily available to the examiner. And they are not found in the parent file 09/113,947.

10           The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by  
15           a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re*  
20           *Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-7, 19-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 09/113,947, now allowed as 6,462,019. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader by including peptidyl aldehydes among other compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is directed to a number of disorders, many of which are notably difficult to treat effectively. Claim 22 is specifically directed to humans. The specification as originally filed provides no written description of treating any of the disorders in any vertebrate including humans.

Applicant's arguments filed 11/19/2002 have been fully considered but they are not persuasive.

Applicants argue that the invention is contemplated as useful where the subject is defined and disorders are listed in the specification.

It is the examiner's position that the specification as originally presented does not teach how to make and use the claimed invention. No written description of the claimed treatment is found in the specification.

Claims 1, 5-7, 19, 22, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PSI, does not reasonably provide enablement for a peptidyl aldehyde. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 the term "a peptidyl aldehyde" lacks enablement as it would require one of ordinary skill in this art undue experimentation to determine which such aldehyde would work in the instant invention.

5           On page 35 Example 3 of the present specification shows data for PSI treating bone, on page 36 an unnumbered table indicates PS1 (not PSI) may be useful for bone formation.

The entire scope of the claims has not been enabled because:

- 10           1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
- 15           3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
- 20           6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.
- In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 11/19/2002 have been fully considered but they are not persuasive.

Applicants argue that only routine experimentation is required to practice the invention where the specification teaches assays to assess proteasomal activity. A declaration is presented that the invention works using the guidance in the specification.

It is the examiner's position that the claims are drawn to ~~❖~~a peptidyl aldehyde~~❖~~ which reads on an essentially infinite number of compounds, and most are unlikely to work in the claimed invention. There is no guidance or direction presented to direct one to determine which aldehydes would work in the broadly claimed invention which is a complex and unpredictable art. Therefore because of the large number of inoperable embodiments claimed, the ordinary artisan would be subjected to undue experimentation to practice the claimed invention.

Regarding the Declaration by Mundy, it shows that there are peptidyl aldehydes that can be assayed and at some concentration induce bone growth in an assay. This rejection is made under 35 USC 112, first paragraph. The declaration does not provide enablement for the invention as claimed because the fact that there are a few aldehydes known that have the desired properties is insufficient to enable one of skill in this art to determine which such aldehydes would work.



**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to

Serial No. 09/421,545  
Art Unit 1651

-9-

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Ralph Gitomer  
Primary Examiner  
Group 1651

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RALPH GITOMER  
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